Government's approval for treatment

†842. SHRIMATI SUSHMA SWARAJ: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that poor children suffering from heart disease and deafness are not getting treatment for want of Centre's approval;

(b) if so, the reasons therefor; and

(c) the total number of children suffering from the said diseases?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) No approval of Central Government is required for treatment of poor children under health care delivery system. However, the Ministry of Health and Family Welfare provide financial assistance to the poor patients for taking treatment for life threatening diseases at different Government Hospitals all over the country under the scheme of (i) Rashtriya Arogya Nidhi (RAN) and (ii) Health Minister's Discretionary Grants (HMDG). Patients suffering from deafness, which is not a life threatening disease, are not eligible for financial assistance under these schemes. All heart cases for financial assistance are considered on priority.

(c) National Sample Survey Organisation Fifty Eighth round (2002) reveals that the prevalence rate of hearing impaired among the children in the age group of 0 to 14 per lakh population is as under:

Age group	Urban	Rural
0-4	55	55
5-9	142	172
10-14	209	196

Rheumatic Heart Disease (RHD) is a major cause of cardiovascular morbidity and mortality in school - age children in developing countries. In an Indian Council of Medical Research study "Jai Vigyan Mission Mode Project on Community Control of RF-RHD", four registries at Chandigarh, Vellore, Kochi and Indore observed prevalence rates ranging from 0.36 to 1.43 per thousand in school children in the age group of 5-14 years. Several other epidemiological studies carried out between 1980 and 2000 observed prevalence rates of 1.0 to 5.4 per thousand school children. It is estimated that approximately 5,09,000 children are suffering from RHD (23.6 % of total population of 1027 million in 5-15 years of age per National Census Data 2001).

Closure of vaccine manufacturing units

843. SHRI M.V. MYSURA REDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Government has decided to close down Government-owned three vaccine manufacturing units in the country;

(b) if so, the reasons for closure of the above vaccine manufacturing units which have been producing vaccines to contain various diseases;

†Original notice of the question was received in Hindi.

(c) whether it is a fact that closing down of the above units will hamper the vaccination programmes;

(d) if so, how the Ministry is planning to go ahead with the vaccination programme;

(e) whether stoppage of vaccine production by above units will lead to price hike or shortage of vaccines in the country; and

(f) if so, what plan the Ministry has in this regard?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) No Sir, The manufacturing licenses of the three Government vaccine units were suspended in January 2008 because of non-compliance of Good Manufacturing Practice.

(c) and (d) No Sir, it is proposed to procure vaccines required for immunization programme from the other manufactures in Public and Private Sector in the country for distribution. The private vaccine manufactures have enough capacity in the country to cater to the requirement of Immunization Programme.

(e) and (f) No Sir, Prices for vaccines are being finalized on the basis of competitive bidding and lowest basis. However, under the immunization programme vaccines are made available to the public from the Government outlets free of cost and as per the current status and the shortage of vaccine is not expected in the country.

Clinical trials in the country

†844. SHRIMATI SUSHMA SWARAJ: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that 139 clinical trials were conducted in the year 2007 in India;

(b) if so, repercussions thereof which have come to the fore; and

(c) the parameters set for selection of foreign drugs for clinical trial in India?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) In the year 2007, the Drugs Controller General (India) has permitted 273 global clinical trials. However, actual number of clinical trials conducted in 2007 in the country is not known, as registration of clinical trials is currently not mandatory.

Recently deaths of 49 children in 42 clinical studies in AIIMS, New Delhi have come to the fore. 6 out of the 42 trials conducted, were funded by pharmaceutical companies and permission for these studies were obtained from DCG(I). There were no deaths in any of these trials.

The Director, AIIMS, New Delhi had constituted a committee to examine the issue of media reports regarding deaths among children in clinical trials. The key finding of the report shows that all studies had scientific rationale and had undergone necessary scientific review. All the study protocols were approved by, the Ethics Committee of AIIMS. None of the deaths reported during clinical studies could be attributed to treatment modality under trial and they were due to the underlying high risk illnesses and serious co-morbid disease conditions that the children suffered from.

†Original notice of the question was received in Hindi.